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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,138	08/30/2001	Wallace K. Dyer	37370-323869 (0200)	9300

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,138

Applicant(s)

DYER, WALLACE K.

Examiner

Jon D. Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 January 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-11,13 and 20-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4,7-11,13 and 20-30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed January 31, 2006 is acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 1, 4, 7-11, 13, 15, 17-29 were pending. Applicants amended claims 1, 13, 20-23, 28 and 29. In addition, Applicants added claim 30 and canceled claims 15 and 17-19. Therefore, claims 1, 4, 7-11, 13 and 20-30 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. The 35 U.S.C. § 112, second paragraph rejection is withdrawn in view of Applicants' declarations and arguments on page 7 of the 1/31/06 Response). That is, Applicant's earlier implicit assertion that e-PTFE is a high-density polyethylene is clearly false as evidenced by Applicant's newly submitted declaration and arguments that recant this position. The Ersek et al. rejection under 35 U.S.C. § 103(a) is withdrawn in view of Applicant's arguments on page 9, paragraphs 2 and 3 and in further view of Applicant's newly submitted declarations. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 102

5. Claims 1, 4, 7, 13, 20-22 and 28-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Bisson (FR 2785811) (Publication date is **May 19, 2000**) (of record).

For *claims 1, 4, 7, 13, 20-22 and 28-30*, Bisson (see entire document) discloses compositions comprising porous microparticles and/or a suspension agent used for soft tissue augmentation (e.g., see Bisson translation, page 1, paragraph 1; see also claim 1, “composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]”), which anticipates the claimed invention. For example, Bisson discloses biocompatible micronized textured polyethylene particles with a size greater than 60 microns (e.g., see Bisson translation, page 4, paragraphs 1-2, “The material which constitutes the microparticles will be ... polyethylene”; see also claim 3, “Composition ... characterized in that the particles have a spherical or ovoid shape with a diameter greater than approximately 10 μm , preferably 30-100 μm [i.e., these are “micronized” particles]”). In addition, Bisson discloses a “textured” microparticles (e.g., see Bisson translation, claim 1, “Composition comprising porous microparticles [i.e., has a “textured” surface] whose pore diameter excludes the penetration of figured elements having a molecular weight of more than 1000 kilodaltons”). Bisson also discloses “high density” polyethylene (e.g., see page 3, “For example, one can use a polymer chosen from ... polyethylene, preferably ‘high density’”). Finally, Bisson discloses a physiological carrier (e.g., Bisson translation, claim 1, “composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]”; see

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also page 5, see also claim 12, “Composition according to any one of Claims 8-10, characterized in that the suspension agent is a liquid or a gel chosen from the polymers of substituted or unsubstituted acrylamide, of vinylpyrrolidone, of hydroxyalkyl acrylate, or the copolymers of substituted or unsubstituted acrylamide and of another molecule bearing a positive electric charge, such as a quaternary ammonium cationic monomer”).

The examiner also notes that the above composition is used for “soft tissue augmentation” and is explicitly injected into soft tissue (e.g., see page 1, paragraph 1, “The present invention concerns compositions comprising porous microparticles and/or a suspension agent ... usable for implantation in a tissue, in particular to increase the volume of this tissue ("soft tissue augmentation"), notably in view of correcting in a lasting manner a deficit in the appearance or the function of this tissue or organ”).

Response

6. Applicant’s arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants’ newly amended and/or added claims and/or arguments.

Applicant argues, “the new declarations, filed concurrently herewith, demonstrate conception of the invention, as recited in the pending claims that recite high density polyethylene particles, and demonstrate conception before the May 19, 2000 publication date of Bisson ...

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Accordingly, Applicant respectfully asserts that the § 102(a) rejection of Claims 1, 4, 7, 13, 20-22, 28 and 29 in view of Bisson has been overcome” (e.g., see 1/31/06 Response, pages 6 and 7).

This is not found persuasive for the following reasons:

The Examiner respectfully disagrees. The declarations (Dyer and Perkins) filed on 1/31/06 under 37 CFR 1.131 have been fully considered but are ineffective to overcome the Bisson reference. First, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Bisson reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Here, the showing of conception is not commensurate in scope with the claims. Specifically, Applicants failed to provide enough evidence to establish conception of the currently claimed “high density polyethylene” genus. Although Dr. Dyer states in his declaration that he conceived of the currently claimed subject matter that “includes” high-density polyethylene microparticles (e.g., see Dyer Declaration, paragraph 5), he never states that he used any other high-density polyethylene microparticle other than MEDPOR (e.g., see paragraph 7). Likewise, the declaration by Dr. Perkins never mentions any other high-density polyethylene. Furthermore, the specification never sets forth a “high-density polyethylene” genus (e.g., see New Matter rejection below). Thus, Applicants have only established, at best, conception for the use of a species falling within the claimed genus i.e., MEDPOR. In support of this argument the Examiner sets forth three references that show high density polyethylene is produced in many

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forms, most of which are not suitable for surgery (e.g., see Wikipedia, the Free Encyclopedia. High density Polyethylene. Retrieved April 23, 2006, pages 1 and 2 showing various forms that are used in Tupperware, milk cartons, plastic bags, etc.; see also POREX Surgical Products Group. MEPOR Biomaterial. Retrieved April 23, 2006, pages 1-12, especially page 2, column 2, “MEDPOR is a biocompatible porous polyethylene material” and page 8, column 2, “MEDPOR BARRIER is made of non-porous high-density polyethylene” showing that high-density polyethylene can be produced in both “porous” and “non-porous” forms; see also Ho, T. “Biopolymers in Otolaryngology” Baylor College of Medicine <http://www.bcm.edu/oto/grand/3312005.htm>, accessed on 4/23/06, pages 1-9, especially, page 4, middle paragraph showing that only “porous” high density polyethylene is used in surgery because it allows “soft tissue ingrowth” and perhaps “limited osseous integration”).

Second, the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Bisson reference (May 19, 2000) to either a constructive reduction to practice (August 30, 2001, see Dyer Declaration, paragraph 7) or an actual reduction to practice (~2002, see Dyer Declaration, paragraph 8). Under 37 CFR § 1.131 Applicant must establish either completion of the invention including an actual reduction to practice prior to the effective date of the reference or conception of the invention prior to the effective date of the reference coupled with due diligence from a time at least just prior to said effective date to a subsequent reduction to practice or to the filing of a U.S. patent application. See 37 CFR § 1.131(b) and *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1617 (Fed. Cir. 1989). Here, Applicants have not provided any evidence showing diligence from a date just prior to the effective date of the reference (i.e., May 18, 2000) until subsequently rejection to practice or to

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the filing of a U.S. patent application (i.e., August 30, 2001 is the earlier of the two dates). Applicant's statement that they were diligent (e.g., see Dyer Declaration, paragraph 6, "I diligently reduced the invention to practice") is not sufficient because it does not address the appropriate dates and it does not set forth any "facts" to corroborate this assertion (e.g., see MPEP § 715.07, "The essential thing to be shown under 37 CFR 1.131 is priority of invention and this may be done by any satisfactory evidence of the facts. Facts, not conclusions, must be alleged. Evidence in the form of exhibits may accompany the affidavit or declaration. Each exhibit relied upon should be specifically referred to in the affidavit or declaration, in terms of what it is relied upon to show").

Accordingly, the 35 U.S.C. § 102(a) rejection cited above is hereby maintained.

Claims Rejections - 35 U.S.C. 112, first paragraph

7. Claims 1, 4, 7-11, 13 and 20-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

Claims 1, 13, 20-23, 28-30 recite the limitation "high-density" polyethylene.

However, the Examiner cannot find support for this genus. Specifically, the specification only recites one species that falls within the genus i.e., solid MEDPOR (e.g., see specification, paragraphs 30, 43 and 58). For example, in *In re Grimme, Keil, and Schmitz* 124 USPQ 499 (CCPA 1960) the Court held that naming one member of a chemical genus (i.e., a single species) is not, in itself, proper basis for a claim to an entire

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chemical genus unless the genus is sufficiently identified in the application by other appropriate language (e.g., see *In re Grimme, Keil and Schmitz* 124 USPQ 499, 501) (“On the other hand, in the case of a small and closely related group such as the halogens, the naming of the group should ordinarily be sufficient since nothing of consequence would be added by also naming each of the well known members of the group”). Here, Applicants failed to “name the group” and thus do not provide any “identifying” language (i.e., the specification does not recite the use of a “high density polyethylene” genus) that would support the claimed genus. Therefore, the disclosure of a single species (i.e., solid MEDPORE) fails to satisfy the test set forth in *In re Grimme, Keil and Schmitz* because Applicants have not provided any “identifying” language and, as mentioned above, a single species is not, in itself, a proper basis for a claim to an entire chemical genus unless such identifying language is set forth in the specification.

Response

8. Applicant’s arguments directed to the above New Matter rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants’ newly amended and/or added claims and/or arguments.

Applicant argues, “in view of these remarks and identified support in the specification [i.e., paragraphs 30, 43 and 58] ... the rejection ... has been overcome” (e.g., see 1/31/06 Response, pages 7 and 8).

This is not found persuasive for the following reasons:

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The Examiner respectfully disagrees. The specification only recites one species (i.e., solid MEDPOR at paragraphs 30, 43 and 58), which does not provide adequate support for the currently claimed “high density polyethylene” genus. For example, in *In re Grimme, Keil, and Schmitz* 124 USPQ 499 (CCPA 1960) the Court held that naming one member of a chemical genus (i.e., a single species) is not, in itself, proper basis for a claim to an entire chemical genus unless the genus is sufficiently identified in the application by other appropriate language (e.g., see *In re Grimme, Keil and Schmitz* 124 USPQ 499, 501) (“On the other hand, in the case of a small and closely related group such as the halogens, the naming of the group should ordinarily be sufficient since nothing of consequence would be added by also naming each of the well known members of the group”). Here, Applicants failed to “name the group” and thus do not provide any “identifying” language (i.e., the specification does not recite the use of a “high density polyethylene” genus) that would support the claimed genus. Therefore, the disclosure of a single species (i.e., solid MEDPORA) fails to satisfy the test set forth in *In re Grimme, Keil and Schmitz* because Applicants have not provided any “identifying” language and, as mentioned above, a single species is not, in itself, a proper basis for a claim to an entire chemical genus unless such identifying language is set forth in the specification.

In further support of this argument the Examiner notes that high density polyethylene is produced in many forms, most of which are not suitable for surgery (e.g., see Wikipedia, the Free Encyclopedia. High Density Polyethylene. Retrieved April 23, 2006, pages 1 and 2 showing various forms that are used in Tupperware, milk cartons, plastic bags, etc.; see also POREX Surgical Products Group. MEDPOR Biomaterial. Retrieved April 23, 2006, pages 1-12, especially page 2, column 2, “MEDPOR is a biocompatible porous polyethylene material” and page 8,

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column 2, "MEDPOR BARRIER is made of non-porous high-density polyethylene" showing that high-density polyethylene can be produced in both "porous" and "non-porous" forms; see also Ho, T. "Biopolymers in Otolaryngology" Baylor College of Medicine <http://www.bcm.edu/oto/grand/3312005.htm>, accessed on 4/23/06, pages 1-9, especially, page 4, middle paragraph showing that only "porous" high density polyethylene is used in surgery because it allows "soft tissue ingrowth" and perhaps "limited osseous integration").

Accordingly, the New Matter rejection cited above is hereby maintained.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.

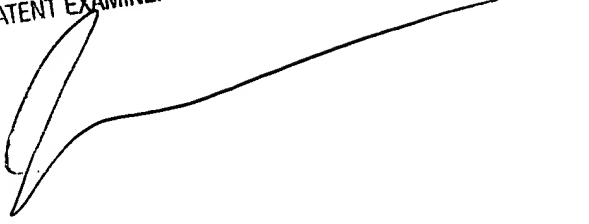
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April 23, 2006

JON EPPERSON, PH.D.
PATENT EXAMINER

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a long, sweeping horizontal line that extends to the right.